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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/613,380

07/03/2003

Wendell Lim

UCSF03-114

5261

23379

7590

04/28/2006

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EXAMINER

SKIBINSKY, ANNA

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 04/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/613,380	Applicant(s) LIM ET AL.	
	Examiner Anna Skibinsky	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 3-5, 7 and 9-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Reply to Applicant

Applicant was required to make two restrictions:

1. Applicant's election of Group I, specie 1A, 2B, 3C (claims 1, 2, 6, and 8) in the reply filed on November 26, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 3-5, 7, 9 are 10-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 26, 2005.
3. Applicant's election with traverse of N-WASP output domain, SH3 and PDZ input domains in the reply filed on February 5, 2006 is acknowledged. The traversal is on the ground(s) that the invention can be applied to essentially any output and input domain providing a desired activity. This is not found persuasive because claim 8 specifically states that the input domain should cooperatively regulate the output domain as an AND-gate. Furthermore, the various domains listed in the specification pertain to different subject matter as different protein domains are classified applied differently in the art of protein engineering.

The requirement is still deemed proper and is therefore made FINAL.

4. Species of output and input domains other than N-WASP output domain, SH3 and PDZ input domains are withdrawn from further consideration pursuant to 37 CFR

1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 5, 2006.

Claim Rejections - 35 USC § 112

VAGUE AND INDEFINITE

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 2, 6, and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claim 1 recites "external, ligand-dependently" which is unclear because it is the input domain that regulates the output domain. The input domains are external to the output domains and so are any binding ligands. The claim can be interpreted as reciting the limitation that input domain regulate the output domain as a result of any externally binding ligand. The claim can also be interpreted as reciting the limitation that input domains externally regulate the output domains. Clarification is requested.

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

SCOPE OF ENABLEMENT

Claims 1, 2, 6, and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an autoregulated protein with an N-WASP output domain, SH3 and PDZ input domains, does not reasonably provide enablement for an autoregulated protein with all of the output and input domains listed in the Tables of the specification. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification does not provide guidance for making an autoregulated protein with a set of interacting input and output domains other than with an N-WASP output domain and SH3 and PDZ input domains. There is insufficient guidance for engineering any autoregulated fusion protein that will “allosterically and external, ligand dependently regulate the output domain.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below which leads to the determination that the above claim lacks enablement due to undue experimentation being required to make and use the invention.

(1) the quantity of experimentation necessary to successfully create a polynucleotide chimera that will express a protein is large. The specification lists a multitude of domains and recites in claim 1 that the protein's input domains will regulate the output domains. Although there is description in the "Detailed Example" (pages 20-27) for the making of function of an autoregulated protein with an N-WASP output domain, SH3 and PDZ input domains, there is insufficient description for how to achieve the synthesis of such an autoregulated protein using all of the domains listed in the specification.

(3) the specification provides a working example describing an autoregulated protein with an N-WASP output domain, SH3 and PDZ input domains. However, there is not a representative sample of experiments to cover the multitude of input and output domains that are recited as being able to comprise such an autoregulated protein. The one Detailed Example is insufficient to describe the making of an autoregulated protein for any of the domains listed in the specification and only describes the one specific autoregulated protein with an N-WASP output domain, SH3 and PDZ input domains.

(4) the nature of the invention is complex and there is insufficient description in the specification to enable the making and use of the multitude of different

autoregulated proteins possible with various combinations of output and input domains listed in the Tables. There is not enough in the specification to enable a general autoregulated protein that will "allosterically and external, ligand-dependently regulate the output domain" for all the domains listed in the specification. The only autoregulated protein described in the specification is one with an N-WASP output domain, SH3 and PDZ input domains. The complexity of creating a fusion protein that will function properly as described in claim 1 warrants more examples and descriptions to enable the invention.

(7) It is highly unpredictable if the combination of domains listed in the specification will successfully lead to an autoregulating protein where the input domains interact with each other and regulate the output domain. Though the idea of creating such a protein is expressed in the specification, there is insufficient evidence that the protein is enabled for all the listed domains.

(8) the breadth of the claim is extremely broad

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anna Skibinsky whose telephone number is (571) 272-4373. The examiner can normally be reached on 8 am - 5:30 pm.

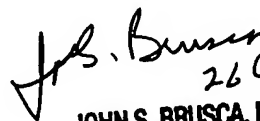
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1631

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Anna Skibinsky, PhD



26 April 2006
JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER